REMARKS

Reexamination and reconsideration of the application as amended are requested.

The examiner's objection to the specification is respectfully traversed. Applicants have amended the specification to provide a descriptive title of the invention as required by the examiner.

The examiner's rejection of claims 1, 3, 6 and 8 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel (US 5,413,550) in view of Watkin (non-patent literature).

Claims 1 and 6 require determining, or a controller which determines, in vivo treatment time as a mathematical function of an experimentally-determined in vitro treatment time. wherein the mathematical function includes blood perfusion rate and patient tissue density. Castel discloses determining, and a controller which determines, treatment time from treatment parameter inputs including tissue depth and tissue temperature increase but does not disclose determining, or a controller which determines, in vivo treatment time as a mathematical function of an experimentally-determined in vitro treatment time. The examiner alleges that the abstract of Watkin teaches conducting studies on in vitro samples to define suitable exposure parameters for a high intensity focused ultrasound procedure in vivo. The examiner also alleges that it would have been obvious to have modified the invention of Castel by using experimentally-determined in vitro treatment times for the controller to determine the in vivo treatment time as taught by Watkin. The applicants respectfully disagree.

The examiner is requested to read the entire Watkin reference provided with the enclosed Supplemental Information Disclosure Statement. The abstract of Watkin actually states, "In vitro experiments with excised porcine kidneys allowed determination of suitable exposure parameters to be tested in vivo." This simply means that in vivo tests were done to verify in vitro experimentally-determined exposure parameters. The entire Watkin reference supports this conclusion. Figure 2 of Watkin plots in vitro experimentally-determined exposure parameters of Intensity versus Exposure Time to produce a thermal lesion. The only

mathematical relationship used by Watkin to relate in vivo to in vitro is that in vivo exposure time equals in vitro exposure time for short exposure times where you do not have to worry about conduction heat loss and perfusion (see Watkin, page 194, column 2, last line to page 195, column 1, line 9). Watkin's used this for his in vivo tests wherein lesions were seen in 13 of 18 kidneys (see the abstract of Watkin). This is not determining an in vivo treatment time from a mathematical function of an experimentally-determined in vitro treatment time, wherein the mathematical function includes blood perfusion rate and patient tissue density, as required by applicants' claims 1 and 6.

Claims 3 and 8 require determining, or a controller which determines, in vivo ultrasound acoustic power as a mathematical function of an experimentally-determined in vitro ultrasound acoustic power, wherein the mathematical function includes blood perfusion rate and patient tissue density. Castel discloses determining, and a controller which determines, ultrasound acoustic power from treatment parameter inputs including tissue depth and tissue temperature increase but does not disclose determining, or a controller which determines, in vivo ultrasound acoustic power as a mathematical function of an experimentally-determined in vitro treatment time. The examiner alleges that the abstract of Watkin teaches conducting studies on in vitro samples to define suitable exposure parameters for a high intensity focused ultrasound procedure in vivo. The examiner also alleges that it would have been obvious to have modified the invention of Castel by using experimentally-determined in vitro ultrasound acoustic power for the controller to determine the in vivo ultrasound acoustic power as taught by Watkin. The applicants respectfully disagree.

From the previous discussion of Watkin, it is clear that Watkin may suggest that in vivo ultrasound acoustic power equals in vitro ultrasound acoustic power for short treatment times, but this is not determining an in vivo ultrasound acoustic power from a mathematical function of an experimentally-determined in vitro ultrasound acoustic power, wherein the mathematical function includes blood perfusion rate and patient tissue density, as required by applicants' claims 3 and 8.

The examiner's rejection of claims 2, 4, 7 and 9 as "obvious", under 35 U.S.C. 103, is respectfully traversed. The examiner rejects these claims as being unpatentable over Castel in view of Watkin and further in view of page 260 of Hill (non-patent literature). Claim 2 depends from claim 1, claim 4 depends from claim 3, claim 7 depends from claim 6, claim 9 depends from claim 8, and applicants' previous remarks concerning the patentability of claims 1, 3, 6 and 8 over Hill in view of Watkin are herein incorporated by reference.

Claims 2 and 7 require a specific equation mathematically relating the in vivo treatment time to form an in vivo lesion to the in vitro treatment time to form an in vitro lesion. The specific equation of clams 2 and 7 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 2 and 7 is not taught by page 260 of Hill because no equation or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo treatment time to in vitro treatment time. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

Claims 4 and 9 require a specific equation mathematically relating the in vivo ultrasound acoustic power to form an in vivo lesion to the in vitro ultrasound acoustic power to form an in vitro lesion. The specific equation of clams 4 and 9 is not taught by page 260 of Hill. Even an equivalent equation to the specific equation of claims 4 and 9 is not taught by page 260 of Hill because no equation or combination of equations of page 260 of Hill mathematically relates, or even can mathematically relate, an in vivo ultrasound acoustic power to in vitro ultrasound acoustic power. The equations (such as equation 1) taught by page 260 of Hill do indeed relate parameters such as ultrasonic power and time and do indeed include terms such as for blood perfusion and tissue density, and such equations may be tested in vivo or in vitro, but such equations do not relate an in vivo ultrasonic power to an in vitro ultrasonic power or an in vivo time to an in vitro time.

Inasmuch as each of the rejections and objections has been answered by the above remarks and amended claims and specification, it is respectfully requested that the rejections and objections be withdrawn, and that this application be passed to issue.

Respectfully submitted,

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